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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,323	02/07/2000	STEFAN NIEWIAROWSKI	6056-236	1775

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/10/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,323

Applicant(s)

NIEWIAROWSKI ET AL.

Examiner

Gabriele E. BUGAISKY

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 13-19, 23 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8, 20-22 and 24-32 is/are rejected.
- 7) ☒ Claim(s) 5, 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-19, 23 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

The disclosure is objected to because of the following informalities:.

This application does not fully comply with 37 C.F.R. 1.821-1.825 as at least one sequence does not appear to have corresponding SEQ ID Nos. For example, RGDX appears on page 38, lines 18 and 19.

The use of trademarks LICROSPHER (e.g., page 31, line 13), TRITON (e.g., page 33, line 15 and page 34, line 4) etc, has been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

Claim 20 is objected to because of the following informalities: "eichistatin" presumably should be "echistatin". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 4, 6, 8-12 20-22 and 24-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1-3, 24-30 and 32, *E. (carinatus)*, VCAM-1, MadCAM-1, CS-1 and HPLC are all abbreviations and are thus deemed indefinite. The full name (e.g., *Echis*. vascular cell adhesion molecule-1, etc.) should appear at the first occurrence of the abbreviation. Claims 25 is included in this rejection as it is a dependent claim and does not clarify the ambiguity.

With respect to the term "biologically active" in claims 4, 6, 8, 9-10 and 20 is so broad as to be essentially useless. Even a fragment of an amino acid has some biological activity. What is encompassed by a biological activity of EC-3 is not defined.

Claims 11-12, 22 are included in this rejection as they depend from claims 4, 6, 8, 9-10 or 20 and do not clarify the ambiguity.

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With respect to claim 20, recitation of amino acid position without reference to a sequence renders a claim indefinite.

Claim 21 is indefinite is it is unclear whether the integrin that binds is a component of venom. If not, then it is suggested that the claims be amended to e.g., "...a peptide from venom that binds to an integrin. . ."

With respect to claims 31-32, it is unclear what is meant by "substantial homology.". How similar must the primary structure of a peptide be to have "substantial homology with SEQ ID NO:2"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 8, 20, 22 and 24-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Vanderslice *et al.* The reference provides peptides that are antagonists of α_4 integrins. The assays included inhibition $\alpha_4\beta_1$ and $\alpha_4\beta_7$ binding to receptors expressed on cell surfaces, such as V-CAM, CS-1 and Mad-CAM. This reference is deemed anticipatory for the claimed subject matter because by sufficient deletions and substitutions, the peptides of Table 1 of the reference could be considered derivatives of EC3 peptides which retain the biological activity of binding to α_4 integrins.

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Claims 4, 6, 8, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by glycine Merck Index). This rejection is based on the recitation of a biologically active fragment. The amino acid is anticipatory for the claimed subject matter because it is a fragment of the disclosed polypeptide(s) and is known to be biologically active.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderslice et al. The reference is discussed above. Although the peptides were shown to be active in preventing binding of α_4 integrins to their substrates (V-CAM, CS-1 and Mad-CAM) in cell lines, the reference did not administer these to an animal. One of skill in the art, however, would expect to administer the peptides of Vanderslice et al. to animals with a reasonable expectation of success in preventing interaction between cells which express α_4 integrins and cells expressing any of V-CAM, CS-1 and Mad-CAM.

Conclusion

No claim is allowed.

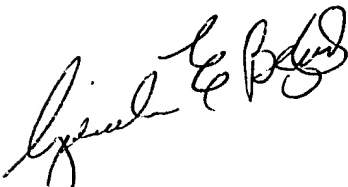
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Claims 5 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.



April 6, 2003

**GABRIELLE BUGAISKY
PRIMARY EXAMINER**

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653